

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:
*The County of Summit, Ohio, et al. v. Purdue
Pharma L.P., et al.*
Case No. 18-op-45090

and

*The County of Cuyahoga v. Purdue Pharma
L.P., et al.*
Case No. 1:18-op-45004

MDL No. 2804

Hon. Dan A. Polster

**MEMORANDUM IN SUPPORT OF
DISTRIBUTOR DEFENDANTS' MOTION FOR
SUMMARY JUDGMENT ON PLAINTIFFS' RICO AND OCPA CLAIMS**

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Distributors¹ hereby seek summary judgment on Plaintiffs’ federal RICO and Ohio Corrupt Practices Act (“OCA”) claims. As explained in other summary judgment submissions, those claims should be dismissed on proximate causation grounds and limited on statute of limitations grounds. As shown below, the RICO and OCA claims fail for two additional, independently dispositive reasons: (1) there is no evidence that Distributors were part of any illicit “enterprise” and (2) there is no evidence that Distributors’ alleged “predicate acts”—*i.e.*, regulatory reporting failures—caused Plaintiffs’ purported injuries.

ARGUMENT

I. THE RICO AND OCA CLAIMS FAIL BECAUSE THERE IS NO EVIDENCE OF AN ILLICIT ENTERPRISE INVOLVING DISTRIBUTORS.

Plaintiffs’ RICO and OCA claims fail for lack of evidence that Distributors associated with—let alone directed the affairs of—an “enterprise.” *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993).²

A RICO enterprise consists of a “group of individuals associated together for a common purpose of engaging in a course of unlawful conduct.” *Robins v. Glob. Fitness Holdings, LLC*, 838 F. Supp. 2d 631, 651–52 (N.D. Ohio 2012) (Polster, J.). A plaintiff can demonstrate the existence of an “association-in-fact” enterprise, as alleged here, “by proving that (1) the associated persons formed an ongoing organization, formal or informal; (2) they functioned as a continuing unit; and (3) the organization was separate from the pattern of racketeering activity in which it engaged.” *Id.* In other words, the plaintiff must prove “ongoing, coordinated behavior among the defendants.” *Begala v. PNC Bank, Ohio, Nat. Ass’n*, 214 F.3d 776, 781 (6th Cir. 2000) (quoting

¹ AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation.

² The standard for establishing the existence of an enterprise under the OCA is the same as under RICO. See, e.g., *State v. Franklin*, Nos. 24011, 24012, 2011 WL 6920727, ¶¶ 90–94 (Ohio Ct. App. Dec. 30, 2011) (collecting cases).

Frank v. D'Ambrosi, 4 F.3d 1378, 1386 (6th Cir. 1993)); *see also Crichton v. Golden Rule Ins. Co.*, 576 F.3d 392, 400 (7th Cir. 2009); *First Capital Asset Mgmt., Inc. v. Satinwood, Inc.*, 385 F.3d 159, 175 (2nd Cir. 2004). In addition to proving the existence of an enterprise with which each defendant associated, a plaintiff must also prove that each defendant played “some part in **directing** the enterprise’s affairs.” *United States v. Fowler*, 535 F.3d 408, 418 (6th Cir. 2008) (emphasis added); *see also Reves*, 507 U.S. at 185 (requiring a defendant to participate in the “operation or management of the enterprise itself”).

Here, there is a complete failure of proof as to Distributors: there is no evidence from which a reasonable jury could infer the existence of an (1) on-going organization involving Distributors, (2) that functioned as a “continuing unit” (3) for the purpose of engaging in unlawful conduct. Nor is there any evidence that a Distributor directed the affairs of any such enterprise. Accordingly, Distributors are entitled to summary judgment on Plaintiffs’ RICO and OCPA claims.³

Plaintiffs allege that members of a so-called “RICO Supply Chain Enterprise”—consisting of certain distributor and manufacturer defendants—“worked together to achieve their common purpose” through the Healthcare Distribution Alliance (“HDA”). Cuyahoga TAC ¶ 514; Summit TAC ¶ 531. HDA is the trade association for the wholesale distributor industry. *See* Ex. 1 at 38:6–18.⁴ Its “core” membership includes thirty-four wholesale distributors. *Id.* at 38:23–39:4. While HDA allows manufacturers and service providers to participate on a limited basis, *see* Ex. 2 at

³ On summary judgment, the moving party need not prove the absence of a genuine issue of material fact, but may instead discharge its burden by pointing out the absence of evidence to support the nonmovant’s case. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). “The mere existence of a scintilla of evidence” in support of the nonmoving party’s position is insufficient to defeat summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

⁴ All Exhibit references are to the declaration of Christian J. Pistilli, submitted herewith.

104:13–18, those limited members cannot participate in—and therefore cannot influence or coordinate with—HDA’s committees focused on government affairs, public policy, or regulatory compliance issues, *see* Ex. 1 at 439:4–17, 441:3–6; Ex. 3 at 46:14–17, 48:18–24.

As a trade association, it would not be surprising if HDA “created a private network” where its members “could form relationships and create alliances ... and hold strategic business discussions,” as Plaintiffs allege. ECF No. 1025, at 9. Nor would it be surprising if HDA pursued the “common interest” of its members, since it is required to do precisely that under federal law (in order to maintain its tax-exempt status). *See* 26 C.F.R. § 1.501(c)(6)-1. But there is ***no evidence*** that Distributors worked together or with Manufacturers through HDA (or otherwise) to achieve any ***unlawful*** common purpose. And, in the absence of such evidence, mere “membership in a trade organization ... does not make [Distributors] part of an enterprise.” *Almanza v. United Airlines, Inc.*, 851 F.3d 1060, 1072 (11th Cir. 2017); *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 380 (3d Cir. 2010) (“[T]hat defendants took advantage of an opportunity to meet provided by a legitimate enterprise in the normal course of its business does not mean—or plausibly imply—that defendants were participating in ... [a RICO] enterprise.”); *Ancil v. Ally Fin., Inc.*, 998 F. Supp. 2d 127, 142 (S.D.N.Y. 2014) (“[M]embership in a trade association hardly renders plausible the conclusion that ... members are functioning as an ongoing, organized, structured [RICO] enterprise.”), *aff’d in relevant part sub nom. Babb v. Capitalsource, Inc.*, 588 F. App’x 66 (2d Cir. 2015); *Moss v. BMO Harris Bank, N.A.*, 258 F. Supp. 3d 289, 301 n.4 (E.D.N.Y. 2017) (same); *see also In re Travel Agent Comm’n Antitrust Litig.*, 583 F.3d 896, 911 (6th Cir. 2009) (“[A] mere opportunity to conspire does not, standing alone, plausibly suggest an illegal agreement because [defendants’ joint] presence at such trade meetings is more likely explained by their lawful, free-market behavior.”).

The Sixth Circuit has stated that “the existence of an association-in-fact [enterprise] is oftentimes more readily proven by what it does, rather than by abstract analysis of its structure.” *Ouwinga v. Benistar 419 Plan Servs., Inc.*, 694 F.3d 783, 794 (6th Cir. 2012). Relying on this proposition, Magistrate Judge Ruiz pointed to allegations that “Manufacturers and Distributors used the HDA” to accomplish various (purportedly) improper ends as sufficient to *plead* the existence of an enterprise. ECF No. 1025, at 38.⁵ But we are now at the summary judgment stage, and so Plaintiffs need *evidence*. There is no record evidence that Distributors joined with Manufacturers or one another—either through HDA or otherwise—to achieve any illicit purpose, as demonstrated by an examination of the categories of conduct alleged in the Complaints.

Lobbying. According to Plaintiffs, Distributors (via HDA) “collectively sought to undermine the impact of the [Controlled Substances Act]” through “lobbying efforts.” Cuyahoga TAC ¶ 897; Summit TAC ¶ 854. But, as explained in Distributor Defendants’ Motion for Summary Judgment on Civil Conspiracy Claim, any alleged lobbying by HDA (or by Distributors directly) is protected under the *Noerr-Pennington* doctrine. That legal rule applies with equal force to Plaintiffs’ RICO claim. Engaging in protected First Amendment petitioning activity is not an unlawful purpose, and the *Noerr-Pennington* doctrine forecloses any attempt to impose liability on Distributors for their purported efforts to influence the federal government (including Congress and DEA) in setting policy relating to the distribution of controlled substances. *See* Mem. In Supp. Dist. Defs.’ Motion for Summary J. on Civil Conspiracy Claim (“Conspiracy Mem.”) (ECF No. 1692-2) at II.A; *see also Sosa v. DirectTV*, 437 F.3d 923, 942 (9th Cir. 2006) (affirming dismissal of RICO claim on *Noerr-Pennington* grounds).

⁵ Distributors did not object to Magistrate Judge Ruiz’s enterprise recommendation, and so this Court has not yet had the opportunity to confront the “enterprise” question.

Production Quotas. The Complaints suggest that Distributors (through HDA) sought to “increas[e] the [opioid production] quotas set by the DEA.” Cuyahoga TAC ¶ 898; Summit TAC ¶ 855. This claim too is foreclosed by the *Noerr-Pennington* doctrine. It also fails because no evidence supports it. To the contrary, the evidentiary record confirms that Distributors play no role in setting, advocating for, or increasing DEA’s opioid production quotas. DEA’s 30(b)(6) representative testified:

Q. Now, do wholesale[rs] such as McKesson, Cardinal and AmerisourceBergen provide any information to DEA that is used to set those quotas?

...

A. Quotas are not related to distributors, so no.

Ex. 4 at 111:12–18, 112:9–13, 112:21–113:1.⁶ There is thus no evidence of any “ongoing, coordinated activity” by Distributors to influence DEA’s production quotas, whether through HDA or otherwise. *See* Conspiracy Mem. at II.B.

Suspicious Order Reporting. Plaintiffs allege that Distributors agreed through HDA not to report “suspicious” orders placed by their customers. No record evidence supports this assertion. *See* Conspiracy Mem. at IV. Even assuming *arguendo* that Plaintiffs are able to identify orders that Distributors improperly failed to report, those reporting failures demonstrate only parallel conduct by independent actors, not an enterprise acting for a common purpose. *See Boyle v. United States*, 556 U.S. 938, 947 n.4 (2009) (recognizing that a RICO enterprise claim must fail where defendants operated “independently and without coordination”); *Am. Dental Ass’n v. Cigna Corp.*, 605 F.3d 1283, 1295 (11th Cir. 2010) (rejecting enterprise allegations where defendants’

⁶ *See also* Ex. 5 at 92:4–6 (confirming for AmerisourceBergen Drug Company that “as a distributor ... we’re not involved with quotas.”); Ex. 6 at 97:15–98:21 (confirming that McKesson Corporation did not lobby or seek to influence DEA on quotas); Ex. 3 at 51:14–52:4 (no “common goals” shared by HDA members “when it comes to drug annual production quotas”).

actions “may just as easily have developed from independent action”).⁷ The record is devoid of evidence that Distributors reached a “coordinated” agreement not to report suspicious orders or that they functioned as a “continuing unit” where reporting is concerned.

Plaintiffs’ assertion that Distributors agreed (through HDA or otherwise) not to report other Defendants’ suspicious orders is likewise unsupported by the evidence. As a practical matter, Distributors do not generally have the *ability* to monitor orders placed with their competitors. *See* Conspiracy Mem. at IV.B. Moreover, as DEA itself has confirmed, Distributors have no duty to report suspicious orders received by others. Ex. 7 at 261:1–19. The suggestion that Distributors reached an illicit agreement not to report orders to DEA that—according to DEA itself—they had no legal obligation to report makes no sense.

Manufacturer Marketing. Plaintiffs’ claims relating to Manufacturer marketing provide no evidence of an “ongoing organization” involving Distributors. As a threshold matter, the Complaints—including Plaintiffs’ recently filed Third Amended Complaints—do not allege that Distributors participated in any marketing-related RICO enterprise. Plaintiffs allege the existence of an “Opioid Marketing Enterprise” whose purported “common purpose” was to “unlawfully increase the demand for opioids” by “downplay[ing] the risk of addiction and exaggerat[ing] the benefits of opioid use”—and whose members consist *only* of Manufacturers. Cuyahoga TAC ¶¶ 987–88; Summit TAC ¶¶ 945–46. Nowhere in the Complaints do Plaintiffs allege that the so-

⁷ *See also United Food & Commercial Workers Unions & Emp’rs Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 855 (7th Cir. 2013) (“The complaint describes conduct that might plausibly state a claim for fraud ... against either defendant, but RICO does not penalize parallel, uncoordinated fraud.... The Fund cannot bootstrap its allegations of illegal conduct into allegations that Walgreens and Par conducted the affairs of an enterprise by asking us to infer that because the activities were illegal, they therefore must also have been coordinated activity undertaken on behalf of the [alleged] enterprise.”); *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 375 (rejecting enterprise liability premised on “competitors who independently engaged in similar types of transactions”).

called “RICO Supply Chain Enterprise”—the only enterprise in which Distributors allegedly participated—played any role in purportedly fraudulent marketing designed to increase demand.

The absence of allegations is matched by an absence of evidence. There is no evidence that Distributors joined a purported RICO enterprise whose purpose was to increase demand for opioids by making false statements to doctors or patients. For example, Plaintiffs’ experts opine at length about the role that Manufacturer marketing and promotion played in altering the standard of care for the treatment of chronic pain, and the resulting increase in opioid prescribing by doctors. *See, e.g.,* Mem. In Supp. Dist. Defs.’ Motion for Summary J. on Proximate Causation Grounds at 8–11. But Plaintiffs’ experts offer “no opinions on distributors.”⁸

At most, Plaintiffs point to instances in which Distributors offered Manufacturers an opportunity to include messages prepared by Manufacturers in various communications.⁹ But the content of ads placed on Distributor-operated platforms was created and controlled by Manufacturers.¹⁰ And as Plaintiffs’ own expert acknowledges, the “vast majority” of those

⁸ *See* Ex. 8 at 94:19–21 (“I have no opinions on distributors”). Similarly, Dr. Mark Schumacher opines that “[t]he medical standard of care for treating both chronic and acute pain was changed because of widespread promotion and marketing of opioids,” Ex. 9 at ¶ 8, but attributes this change only to Manufacturers, *see* Ex. 10 at 186:5–24. Dr. Anna Lembke offers the opinion that “opioid overprescribing ... has been driven by a wholesale shift in medical practice,” Ex. 11 at 12, but limits her opinions to Manufacturers, Ex. 12 at 274:12–20, 275:7–13. Dr. Meredith Rosenthal opines that the “unlawful” marketing by Manufacturers caused opioid prescribing to increase, Ex. 13 at ¶ 11, but her analysis does not focus on distributors, Ex. 14 at 750:2–6. Dr. Matthew Perri testified that he has no opinions specific to any particular Distributor. *See* Ex. 15 at 204:18–205:14.

⁹ None of Plaintiffs’ experts cites evidence that Distributors agreed to disseminate, or did disseminate, any of the “falsehoods” allegedly perpetuated by Manufacturers. And there is no evidence of any agreement by Distributors to knowingly provide any false information. *See* Conspiracy Mem. at III.

¹⁰ *See, e.g.,* Ex. 16 at 191:17–20 (Purdue witness testifying that “[Distributors] couldn’t change a comma on what was being sent out”); Ex. 17 (“The content of any graphical ad is the sole responsibility of Purdue Pharma ... [which] represents and warrants that the graphical ad complies with all applicable laws.”); Ex. 18 at 58:5–59:7, 61:3–12 (“The material is authored by the supplier, not by AmerisourceBergen.”); Ex. 19 (“[Manufacturer] shall be fully responsible for the form and content of such e-mail communication as set forth in the Master Services Agreement.”).

messages were not intended to drive patient- or physician-level demand for opioids (the alleged purpose of the “Opioid Marketing Enterprise”), but rather “focused generally on price, availability, and other features of interest to pharmacy and other buyers.”¹¹

These “routine business relationships” between certain Distributors and Manufacturers fall far short of establishing the existence of a RICO enterprise in which Distributors participated. *Robins*, 838 F. Supp. 2d at 653 (collecting cases); *see also VanDenBroeck v. CommonPoint Mortg. Co.*, 210 F.3d 696, 700 (6th Cir. 2000), *abrogated on other grounds by Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008) (rejecting RICO enterprise claim where plaintiffs’ allegations “indicate nothing more than that [defendant] had a business relationship with the” alleged co-members of the enterprise); *In re Duramax Diesel Litig.*, 298 F. Supp. 3d 1037, 1080 (E.D. Mich. 2018) (an enterprise “must be predicated on a relationship more substantial than a routine contract between a service provider and its client”).¹²

The Seventh Circuit’s opinion in *Walgreen Co.* is instructive. There, plaintiffs alleged a RICO enterprise consisting of Par, a drug manufacturer, and Walgreens, a chain pharmacy, whose common purpose was to boost pharmaceutical sales. 719 F.3d at 854. The court proceeded from the assumption that both Walgreens and Par had engaged in unlawful conduct. *Id.* at 855. It also

¹¹ See Ex. 20 at ¶ 185; *see also* Ex. 15 at 224:19–20 (“The wholesalers do not generate patient level demand, no.”).

¹² See also *Ray v. Spirit Airlines, Inc.*, 836 F.3d 1340, 1352 n.3 (11th Cir. 2016) (rejecting enterprise claim premised on defendants’ commercial relationship as “wholly insufficient”); *Bible v. United Student Aid Funds, Inc.*, 799 F.3d 633, 655–56 (7th Cir. 2015) (rejecting enterprise allegations based on “a run-of-the-mill commercial relationship”); *Parm v. Nat’l Bank of Cal., N.A.*, 242 F. Supp. 3d 1321, 1348 (N.D. Ga. 2017) (“[T]he statutory requirements of RICO cannot be circumvented by attempting to characterize a routine contractual relationship for services as an independent enterprise.”); *Singh v. NYCTL 2009-A Trust*, No. 14 Civ. 2558, 2016 WL 3962009, at *10 (S.D.N.Y. July 20, 2016) (“[T]he mere existence of routine business relationships among the defendants is insufficient to establish an ‘enterprise’ under RICO.”), *aff’d*, 683 F. App’x 76 (2d Cir. 2017); *Gomez v. Guthy-Renker, LLC*, No. EDCV 14-01425, 2015 WL 4270042, at *9, *11 (C.D. Cal. July 13, 2015) (“Courts have overwhelmingly rejected attempts to characterize routine commercial relationships as RICO enterprises.”).

recognized that “Walgreens and Par were not strangers” and “regularly communicated with one another” in order to facilitate Walgreens’ “purchase [of] generic” drugs, but concluded that these interactions were *not* evidence of an enterprise. *Id.* As the court explained, these facts “show[ed] only that the defendants had a commercial relationship, not that they had joined together to create a distinct entity for purposes of improperly filling ... prescriptions.” *Id.* Likewise here, the fact that Distributors offered pharmaceutical manufacturers certain fee-for-service opportunities to include information about their products in communications with Distributors’ pharmacy customers is evidence of a routine commercial relationship, not a criminal enterprise.¹³

At bottom, Plaintiffs’ liability theory is that Distributors “violated RICO by having [Manufacturers] as a customer”—a theory the Sixth Circuit has specifically rejected. *McNew v. People’s Bank of Ewing*, No. 92-5675, 1993 WL 243772, at *6 (6th Cir. July 6, 1993) (concluding that evidence of commercial transactions is a “woefully inadequate” basis for enterprise liability). Other courts likewise have rejected enterprise claims premised on “garden-variety marketing arrangement[s].” *See, e.g., Crichton*, 576 F.3d at 399 (“Allegations that a defendant had a business relationship with the putative RICO enterprise or that a defendant performed services for that enterprise do not suffice.”); *In re Duramax*, 298 F. Supp. 3d at 1079–80 (enterprise “must be predicated on a relationship more substantial than a routine contract between a service provider and its client”). This Court should do the same.

¹³ For much the same reasons, there is also no evidence that Distributors played any role in *directing* the affairs of any marketing-related enterprise. *See Goren v. New Vision Int’l, Inc.*, 156 F.3d 721, 727–28 (7th Cir. 1998) (finding that “distribut[ion] promotional materials” established “the existence of a business relationship ... but do[es] not indicate that ... defendants took some party in directing [alleged enterprise’s] affairs”); *Univ. of Md. at Baltimore v. Peat, Marwick, Main & Co.*, 996 F.2d 1534, 1539 (3d Cir. 1993) (“Simply because one provides goods or services that ultimately benefit the enterprise does not mean that one becomes liable under RICO as a result.”); *Chi v. MasterCard Int’l*, No. 14-cv-614-TWT, 2014 WL 5019917, at *2 (N.D. Ga. Oct. 7, 2014) (“Simply providing ... services or processing ... transactions is not enough to establish ‘operation or management’ of an enterprise.”); *see also Reves*, 507 U.S. at 185; *Fowler*, 535 F.3d at 418; *Walgreen Co.*, 719 F.3d at 856.

Expanding the Market. Plaintiffs allege that “Defendants collaborated to expand the opioid market in an interconnected and interrelated network ..., including, for example, membership in [HDA].” Cuyahoga TAC ¶ 809; Summit TAC ¶ 763. There is no record evidence that Distributors were part of an ongoing organization whose purpose was to “expand the market” for prescription opioids. *See supra* pp. 6-9. But even if there were, expanding the market for a legal product is not itself an unlawful purpose. *See, e.g., Ray*, 836 F.3d at 1352 n.3 (“[S]ince making money is the purpose of every for-profit corporation ... this purpose is wholly insufficient to establish an association-in-fact enterprise.”); *Green v. Morningstar Inv. Mgmt. LLC*, No. 17 C 5652, 2019 WL 216538, at *3 (N.D. Ill. Jan. 16, 2019) (“Green failed to distinguish between the illicit purpose of the enterprise and the lawful purpose of the defendant businesses. There is nothing inherently nefarious about the defendants wanting ... to maximize their profits.”); *see also Baseball at Trotwood, LLC v. Dayton Prof’l Baseball Club*, No. C-3-98-260, 2003 WL 25566103, at *19 (S.D. Ohio Sept. 2, 2003) (holding that because “the pursuit of profit is not unlawful, concerted actions taken in furtherance of such do not give rise to any liability”).

* * *

In sum, Plaintiffs have ***no evidence*** that Distributors associated with Manufacturers or one another, as part of a continuing unit, for the “common purpose of engaging in a course of unlawful conduct.” *Robins*, 838 F. Supp. 2d at 651–52. For this reason alone, Distributors are entitled to summary judgment on the RICO and OCPA claims.

II. THE RICO AND OCPA CLAIMS FAIL BECAUSE THERE IS NO EVIDENCE THAT DISTRIBUTORS' PURPORTED PREDICATE ACTS CAUSED PLAINTIFFS' INJURIES.

Plaintiffs' RICO and OCPA claims cannot survive summary judgment for an additional reason: there is no evidence that Distributors' alleged predicate acts—*i.e.*, their alleged failure to report certain “suspicious orders” to regulators¹⁴—caused Plaintiffs' injury.

RICO and the OCPA impose liability based *only* on the commission by defendants of enumerated “predicate acts” (*e.g.*, mail and wire fraud)—not simply for conduct that might otherwise be characterized as wrongful or tortious. *See* 18 U.S.C. §§ 1961(1), 1962(c); Ohio Rev. Code §§ 2923.31(I), 2923.34(A). While Plaintiffs suggest, for example, that Distributors' shipments of certain orders were wrongful, Plaintiffs do not assert that driving trucks containing prescription medications to Ohio pharmacies is a predicate act under RICO or the OCPA—nor could they. Instead, the only predicate offenses potentially at issue here are Distributors' alleged failures to *report* certain “suspicious” orders to DEA and BOP. *See* Cuyahoga TAC ¶ 960; Summit TAC ¶¶ 917–18.¹⁵

¹⁴ Plaintiffs alleged—and Magistrate Judge Ruiz accepted at the motion to dismiss stage—that a knowing failure to report a suspicious order to DEA is a RICO “predicate act” because it constitutes an “offense involving ... the felonious ... concealment, buying, selling, or otherwise dealing in a controlled substance.” 18 U.S.C. § 1961(1)(D); *see* ECF No. 1025, at 44–47. Distributors respectfully submit that is wrong as a matter of law. Distributors also submit that there is no evidence that they knowingly “concealed” any shipments from DEA; the record reflects that Distributors reported *all* of their opioid shipments (including the purportedly “suspicious” ones) to DEA via the ARCOS database. *See infra* p. 13. Nonetheless, Distributors assume *arguendo*, for purposes of this motion, that the failure to report a suspicious order can constitute a predicate act of racketeering for purposes of RICO and the OCPA.

¹⁵ Although Plaintiffs also have alleged that Distributors engaged in mail and wire fraud by transmitting routine business documentation that facilitated or supported its shipments to pharmacies, *see, e.g.*, Cuyahoga TAC ¶ 907, Summit TAC ¶ 864, they do not even attempt to support that allegation with any *evidence*. As an initial matter, there is no evidence that Distributors intended to defraud Plaintiffs in any way. *See, e.g., United States v. Daniel*, 329 F.3d 480, 485 (6th Cir. 2003) (mail and wire fraud require an “intent to deprive a victim of money or property”). Nor is there any evidence that these routine business documents were “incident to an essential part of the scheme” or “a step in [the] plot.” *See Schmuck v. United States*, 489 U.S. 705, 710–11 (1989) (internal quotations omitted). Setting aside Distributors'

To survive summary judgment on their RICO and OCPA claims, Plaintiffs must present sufficient evidence that “a RICO predicate offense not only was a ‘but for’ cause of [their] injury, but was the proximate cause as well.” *Hemi Grp. v. City of New York*, 559 U.S. 1, 9 (2010); *accord Herakovic v. Catholic Diocese of Cleveland*, No. 85467, 2005 WL 3007145, at *5–6 (Ohio Ct. App. Nov. 10, 2005) (applying same rule to OCPA claims). Any assertion that Distributors’ alleged reporting failures caused Plaintiffs’ harm is necessarily premised on the unfounded assumption that DEA (or the Ohio Board of Pharmacy (“BOP”)), in response to increased reports, would have acted to prevent Plaintiffs’ harm. Not only is Plaintiffs’ causal theory speculative, it is belied by the undisputed record evidence. Plaintiffs’ claims therefore cannot survive summary judgment.

The CSA’s implementing regulations require registrants to design and operate systems to report as “suspicious” “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b). As DEA has acknowledged, this standard is “subjectiv[e],” Ex. 7 at 184:21–185:2; *see also* Ex. 21 at 89:13–22; Ex. 22 at 106:5–15, and orders that might be considered “suspicious” under the regulation are not necessarily at risk of diversion.¹⁶ Indeed, DEA acknowledges that an unknown number of suspicious orders reports were “false positives” flagging perfectly legitimate orders. Ex. 22 at 208:5–24.

alleged regulatory reporting violations, Plaintiffs have no evidence that any Distributor committed two or more predicate acts, as required under RICO and the OCPA. *See* 18 U.S.C. § 1961(5); Ohio Rev. Code § 2923.31(E).

¹⁶ Ex. 22 at 162:23–163:7 (“Q. ‘Just because a customer has been identified as having transacted one or more purchases ... the distributor deems suspicious, does not mean that activity was illicit in any manner.’ ... [Do] you agree? ... A. Yes.”); Ex. 7 at 307:20–308:2 (“Q. [If] an order ... is unusually large, does that order necessarily lead to diversion? A. ... [I]t may or it may not.”).

Plaintiffs lack any evidence that Distributors’ alleged failure to report “suspicious” orders to DEA caused their injuries. Plaintiffs’ causal theory rests entirely on the assumption that, had Distributors reported such orders, DEA would have taken action to prevent downstream harm. That theory is baseless because Distributors undisputedly reported all of the pharmacy orders they shipped—including the ones that Plaintiffs now purport to identify as “suspicious”—to DEA.

As Plaintiffs’ experts admit, *Distributors reported their shipments of opioids to DEA* in real time via the ARCOS reporting system. *See, e.g.*, Ex. 23 at ¶ 47; Ex. 24 at 14–15. There is no evidence that any Distributor failed to report, as required, every shipment of opioid medications to pharmacy customers in the Plaintiff counties (or elsewhere). To the contrary, Plaintiffs’ expert has opined that the ARCOS database is 99 percent accurate. Ex. 23 at ¶ 71.

Armed with the ARCOS database, DEA knew the total volume of prescription opioids being shipped into each state, county, and pharmacy—including Summit and Cuyahoga counties. *See, e.g.*, Ex. 25 at 24:23–25:5.¹⁷ DEA thus had notice when “excess” pills were being shipped either to particular pharmacies within the counties or to the counties in the aggregate. Because it included *all* orders, the ARCOS data reported by Distributors to DEA necessarily included any allegedly suspicious orders. Ex. 7 at 326:6–329:19; Ex. 22 at 542:4–543:11.

The ARCOS data was inherently superior to the “subjective” suspicious order reports submitted by DEA registrants, and provided DEA with all of the information it needed to identify illicit or suspicious order patterns. Ex. 22 at 171:9–172:1, 537:17–539:7. Indeed, DEA itself

¹⁷ Since at least 2008, all orders that Distributors have identified as “suspicious” have been blocked from shipment. *See* Ex. 5 at 32:7–15; Ex. 26 at 72:3–73:9; Ex. 27 at 129:4–14. Even if some of these blocked “suspicious” orders were not reported, there can be no dispute that those orders did not cause Plaintiffs’ alleged injuries. As Plaintiffs’ expert James Rafalski acknowledged, whether reported or not, blocked orders “remain[] safely” at the distributors’ warehouse and do not “have the potential to be diverted.” Ex. 28 at 368:6–13, 370:15–24.

acknowledged that, in light of the ARCOS data, it “didn’t need” suspicious order reports at all. *Id.* at 544:1–11 (former DEA Unit Chief testifying that DEA “didn’t need distributors’ suspicious order reports” in order to “identify pharmacies” with suspicious ordering). Thus, Distributors’ alleged failure to report “suspicious” orders to DEA could not have had any material impact on DEA’s anti-diversion efforts: DEA already had access to precisely the information it needed investigate potential diversion, in a format that DEA itself acknowledged was more helpful to it than the suspicious order reports.

Moreover, even if Distributors had submitted additional suspicious order reports, those reports do not automatically trigger a DEA investigation. *See* Ex. 7 at 558:8–17; Ex. 22 at 164:9–15. Rather, after receiving a suspicious order report, the relevant DEA field office has ***complete discretion*** to open a full-blown investigation or do nothing at all. Ex. 22 at 146:1–24, 167:13–25; Ex. 25 at 156:10–157:9. Most often, DEA did nothing—it confirmed during discovery that “half to three-quarters” of the reports submitted to its Excessive Purchase System “went into the trash can.” Ex. 22 at 84:9–21.¹⁸ Because Plaintiffs’ causal theory rests on the assumption that DEA would have taken a purely discretionary act, it fails as a matter of law. *Dow Chem. Co. v. Exxon Corp.*, 30 F. Supp. 2d 673, 695 (D. Del. 1998) (rejecting RICO claim where patent agency “has discretion whether or not to grant patent property rights and declare interferences and it is only those intervening decisions that connect Exxon’s allegedly fraudulent misrepresentations to the losses suffered by Dow”); *Barr Labs., Inc. v. Quantum Pharmics, Inc.*, 827 F. Supp. 111, 116 (E.D.N.Y. 1993) (“The alleged racketeering predicates were not the proximate cause of Barr’s

¹⁸ From 2007 to 2017—a period during which DEA received more than 1.2 million suspicious order reports from DEA registrants (including Distributors), Ex. 7 at 555:20–556:11—DEA issued only 254 immediate suspensions and 638 orders to show cause. *Id.* at 577:18–581:23. That means that, even assuming *every* such action was initiated by receipt of a suspicious order report (an incredibly unlikely assumption), DEA took action on fewer than 1% of the suspicious order reports it received. *Id.* at 582:2–583:14.

injury” where its “losses depend on the intervening actions of the FDA,” which “had discretion in deciding whether or not to issue the licenses” in question); *Lifschultz Fast Freight, Inc. v. Consol. Freightways Corp. of Del.*, 805 F. Supp. 1277, 1291 (D.S.C. 1992) (rejecting RICO claim where “[a]ny harm from the alleged conspiracy would be purely contingent on how the rate bureaus and the ICC acted based on the alleged predicate acts”), *aff’d*, 1993 WL 241742 (4th Cir. July 6, 1993).

Finally, even if DEA had taken action in response to a suspicious order report, there is no evidence that such action would have prevented Plaintiffs’ claimed injuries. To the contrary, the record reflects that DEA’s limited enforcement actions were inadequate. For example, in 2002, the Inspector General of the U.S. Department of Justice concluded that “DEA’s enforcement efforts have not adequately addressed the problem of controlled pharmaceutical diversion.” Ex. 29 at ii-iii.¹⁹

In short, the evidence establishes that—even if Distributors had submitted additional suspicious order reports—DEA would not have needed them to investigate potential diversion or criminal activity, and most would have ended up in “the trash can.” At a minimum, Plaintiffs have no evidence that (1) DEA would have investigated the “suspicious” orders Distributors allegedly failed to report; (2) that upon investigation, those orders would have proven to be linked to diversion or illicit activity; (3) that DEA would then have pursued some enforcement action; and

¹⁹ Like DEA, the Ohio BOP is not required to investigate any suspicious order report it receives. *See* Ex. 30 at 181:10–23. The decision to launch an investigation is entirely within the BOP’s discretion. *See id.* at 187:3–6. Moreover, the BOP has confirmed that it never initiates an investigation based simply on the submission of a suspicious order report—other confirmatory information is required. *See id.* at 259:19–25. The BOP has explained that not all suspicious order reports need to be investigated because many relate to entirely legitimate orders that are not at risk of diversion. *See id.* at 186:19–187:2 (“We can’t tell just by this [suspicious order report] that this is a suspicious order.”). Moreover, like DEA, the BOP has other tools—such as the State’s OARRS system—through which it can access and analyze statewide, prescriber level data in order to identify illicit activity or prescribing habits. *See* Ex. 31 at 82:17–84:23, 96:3–10, 134:10–20, 158:8–16.

(4) that such enforcement action would have successfully averted some of Plaintiffs' injuries. Lacking such evidence, Plaintiffs' RICO and OCPA claims fail as a matter of law.

CONCLUSION

For the foregoing reasons, Distributors are entitled to summary judgment on Plaintiffs' RICO and OCPA claims.

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CERTIFICATE OF SERVICE

I, Geoffrey E. Hobart, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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